AMERICAN FEED INDUSTRY ASSOCIATION

September 24, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

Re: Docket No. 99N-1591; Animal Drug Availability Act; Veterinary Feed Directive

Dear Sir or Madam:

The American Feed Industry Association (AFIA) is the national trade association for feed and pet food manufacturers, ingredient manufacturers and suppliers, equipment manufacturers and other firms which supply goods and services to the feed industry. AFIA members manufacture 75% of the nation's primary, commercial feed, and use Veterinary Feed Directive (VFD) animal drugs. Therefore, AFIA members have a direct interest in this proposed rule.

Introduction

AFIA generally applauds the agency's proposed rule as keeping to the spirit and letter of the statute regarding VFD. AFIA notes, that in the preamble to the rule, FDA states certain new animal drugs in feed should only be administered with a veterinarian's supervision. AFIA endorses this concept and previously worked with FDA to develop the VFD provisions of the Animal Drug Availability Act.

Following the FDA approval of the first VFD animal drug, AFIA cooperated with a coalition of producers, veterinarians and FDA to develop a wide-ranging education program for both the feed industry and producers. The result of the program is a historically high level of compliance for a new medicated feed program. AFIA looks forward to development of additional education programs for new VFD drugs and offers its expertise and resources in planning and production of a national satellite video teleconference once a final rule is adopted.

The Original Signed VFD Form Should Be Presented To The Feed Supplier

The proposed rule would allow the use of telefacsimiles (faxes) to transmit the VFD forms (proposed § 558.6 (b)(4)) to either the client (producer) or distributor (feed mill). The agency requests information and views in the preamble about use of other electronic transmission means, such as via telephone or e-mail. Oversight by a veterinarian is the underlying reason that Congress -- with the support of FDA and AFIA -- created the new

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1501 Wilson Blvd., Suite 1100, Arlington, VA 22209
Tel: 703/524-0810 FAX: 703/524-1921 E-mail: afia@afia.org www.afia.org

category of VFD drugs and feeds. AFIA believes much of this oversight is lost in allowing electronic transmission of the VFD form. For this reason, AFIA opposes all forms of transmission of the VFD except the physical presentation of an actual original VFD signed form by the veterinarian to the producer, and subsequently by the producer to his feed supplier.

AFIA realizes this may place some burden on the producer and veterinarian due to distances between and among the veterinarian, producer and feed mill. However, based on experience to date with the first VFD drug, AFIA is concerned about the potential for misuse of a legitimate VFD form by forwarding the form (by any electronic means) to multiple feed mills. This potential for misuse, which is beyond the control of the mills, would undermine the public health basis for VFD drugs and feeds, namely veterinarian involvement in, and oversight of, the use of the drug. This potential for misuse is easily eliminated by requiring presentation of a signed, original VFD by the producer to his/her feed supplier.

As noted, AFIA's opposition to the electronic transmission of VFD forms is based on the potential for misuse. Until better electronic security systems are developed and implemented, AFIA believes no electronic method of transmission should be permitted. However, AFIA would consider supporting specific means of electronic transmission of VFD forms if security systems were sufficient to prevent fraud. Such security systems would have to prevent the multiple transmission of the same VFD form to multiple suppliers and allow for traceback of such forms.

Tilmicosin's sponsor should be applauded for producing triplicate, *numbered* VFD forms for use by veterinarians. AFIA believes the numbered VFD form is important in controlling use of VFD drugs and urges FDA to strongly encourage, if not require, the use of such numbered forms by VFD drug sponsors. These numbered forms will lessen the regulatory burden on feed mills and provide a more thorough means of traceback for any potential misuse of a VFD form. However, in the absence of a rule requiring physical representation of the original form, this method of control can be easily subverted.

FDA should remove references to faxes in the proposed rule, and should not allow transmission of VFD forms by any electronic means.

FDA Should Further Examine the Automatic Categorization of VFD Drugs

AFIA is concerned about FDA's designation of all VFD drugs as Category II animal drugs as proposed in § 558.3 (b)(1)(ii). There is no justification or explanation in the preamble for this action. The statute does not require such an action. Although VFD drugs

are expected to be therapeutic in nature, this does not predispose the drug to have a withdrawal time if the drug sponsor supplies data necessary to justify that the drug does not require a withdrawal time.

FDA should re-examine the automatic designation of VFD drugs as Category II drugs.

Summary and Conclusions

AFIA believes this proposed rule generally follows the statute, but we oppose allowing faxes or other electronic means of transmitting a VFD form, as this will considerably lessen the regulatory control over VFD drug use.

FDA should further examine the automatic categorization all VFD drugs as Category II drugs.

AFIA appreciates the agency's consideration of these comments.

Sincerely,

Richard Sellers
Director, Feed Control & Nutrition

cc: Dr. Stephen Sundlof, CVM (HFV-1)
Dr. G. A. (Bert) Mitchell, CVM (HFV-1)
Dr. George Graber, CVM (HFV-220)
Mr. Paul Bachman, AAFCO

AMERICAN FEED INDUSTRY ASSOCIATION
1501 WILSON BLVD. • SUITE 1100 • ARLINGTON, VA. 22209-2403

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AMERICAN FEED INDUSTRY ASSOCIATION
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1501 Wilson Boulevard, Suite 1100
Arlington, VA 22209-2403

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